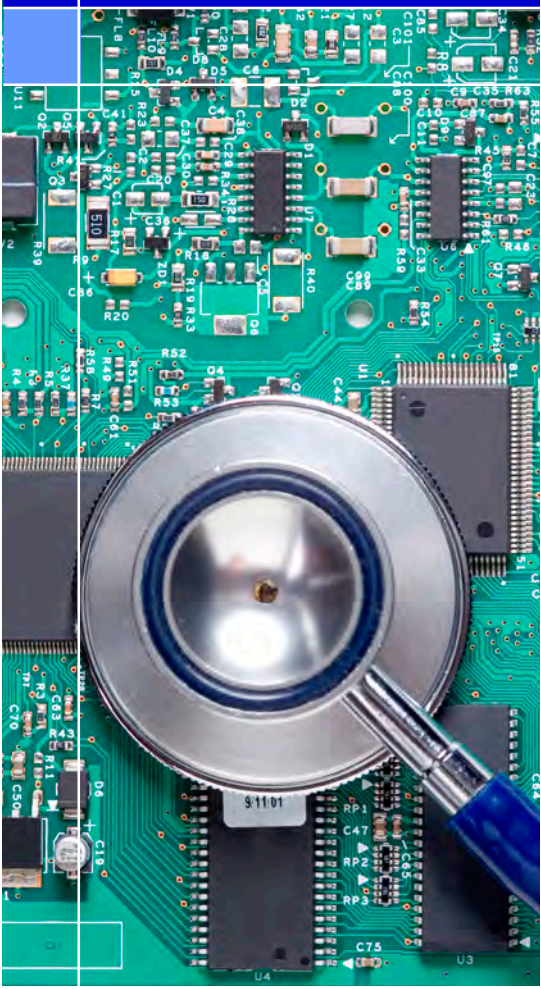
iNEMI Medical Electronics Initiatives



Collaborating to address common challenges

Medical products increasingly rely on electronics for functionality and pose a unique set of reliability and operating challenges.

Through our roadmapping activities, discussions with our members and industry workshops, iNEMI has identified key issues to be addressed collaboratively and has organized several projects that are defining industry-standard solutions to common problems such as reliability, component specifications and supply chain development.

For more information:
Bill Bader
(bill.bader@inemi.org)

Implantable & wearable devices

Component Specifications for Medical Products — define a set of component-level reliability qualification methods for electronic components used in implantable and wearable medical devices. The goal is to develop specifications that are acceptable to device OEMs and supported by component suppliers.

Reliability Requirements for Implantable Medical Devices — define reliability testing for implantables. Current standards are based on high-reliability products typically deployed in harsh environments, and may lead to over-engineered products. At the same time, they do not reflect the specific requirements of implantable devices and can lead to under-estimation of specific failure mechanisms. This multi-phase project will review reliability standards relevant to implantable medical electronic devices, analyze gaps, develop protocols and recommend methodologies.

In the area of medical electronics, iNEMI's goal is to facilitate technology development and deployment to enable medical electronics to provide the patient and medical community with seamless end-to-end solutions for improved health.

Qualification Methods for Portable Medical Products — will develop a reliability qualification method for portable electronic medical equipment, including the peripheral products of implantable systems. The rapid growth of the use of electronics in medical devices and the recent market-driven need to shorten time to market for new products have revealed the lack of a consistent approach for determining the reliability performance of portable devices. As a result, time-consuming and redundant testing occurs at many stages of the product development and qualification cycle. A standard methodology and qualification procedure will enable changes to be made more quickly and products brought to market in a shorter time.

Supply Chain Support of Medical Products — will focus on collecting and publishing widely available information about component and supplier capabilities. It will also develop OEM/supplier business models and operating agreements (e.g., identify/develop best known methods templates).

In Development

Two initiatives — identified at iNEMI workshops — are in the formation stages. One will address the challenge of compatibility between MRIs/X-rays and implantable devices. A second will focus on common qualification methods for medical flex circuits, evaluating common tests — such as bend radius — and identifying common use conditions.

Advancing manufacturing technology

Headquarters
2214 Rock Hill Road
Suite 110
Herndon, Virginia USA
20170-4214
Phone: +1 703-834-0330
Fax: +1 703-834-2735

Additional Locations
Shanghai, China
Limerick, Ireland
Tokyo, Japan

Internet
www.inemi.org
infohelp@inemi.org

iNEMI
International Electronics Manufacturing Initiative